2002

Promotion of prescription medicines: a critical review and research agenda

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Direct to consumer advertising (DTCA) of prescription medicines has generated considerable controversy in both New Zealand and the United States, the only two countries that currently permit promotion ofrestricted medicines. Arguments against DTCA include the effect this may have on doctor-patient relationships, its implications for drug costs, and the extent to which it fully informs potential patients. Conversely, proponents of DTCA claim that it increases knowledge of a variety of common medical conditions, thus fostering earlier diagnosis and better compliance with treatments. However, although arguments for and against DTCA have merit, neither side has supported its position with empirical evidence. In particular, the extent to which DTC promotions communicate effectively and achieve their objective of improving wider consumer knowledge remains unclear. This paper critically evaluates the alleged effects of DTCA and outlines our research agenda, which is designed to bridge current knowledge gaps and provide a more informed basis for public policy decisions.

Disciplines

Arts and Humanities | Life Sciences | Medicine and Health Sciences | Social and Behavioral Sciences

Publication Details

Hoek, J., Gendall, P., Holdershaw, J. , Jones, S. C., and Rossiter, J. R. & (2002). Promotion of prescription medicines: A critical review and research agenda. In R. Shaw, S. Adam & H. McDonald (Eds.), Proceedings of the Australian and New Zealand Marketing Academy Conference, 2-4 December 2002 (pp. 2221-2227). Melbourne, Australia: Deakin University.

Promotion of Prescription Medicines: A Critical Review and Research Agenda

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Abstract

Direct to consumer advertising (DTCA) of prescription medicines has generated considerable controversy in both New Zealand and the United States, the only two countries that currently permit promotion of restricted medicines. Arguments against DTCA include the effect this may have on doctor-patient relationships, its implications for drug costs, and the extent to which it fully informs potential patients. Conversely, proponents of DTCA claim that it increases knowledge of a variety of common medical conditions, thus fostering earlier diagnosis and better compliance with treatments. However, although arguments for and against DTCA have merit, neither side has supported its position with empirical evidence. In particular, the extent to which DTC promotions communicate effectively and achieve their objective of improving wider consumer knowledge remains unclear. This paper critically evaluates the alleged effects of DTCA and outlines our research agenda, which is designed to bridge current knowledge gaps and provide a more informed basis for public policy decisions.

Introduction

Only New Zealand and the United States currently permit direct-to-consumer advertising (DTCA) of prescription medicines, a regulatory initiative that has attracted trenchant criticism in both countries. In New Zealand, DTCA arguably evolved because statutes governing the promotion of medicines did not specifically prohibit it. Other countries (for example, Australia, Canada and EU nations) are considering relaxing their restrictions on DTCA, in part motivated by regulators' awareness of the fact that many consumers are already exposed to U.S.-originated DTCA through the Internet (Erickson, 2000). However, the specific impetus to develop DTC arose from three sources.

First, pharmaceutical companies have found it increasingly difficult and expensive to reach doctors (Morris and Griffen, 1992). The ability to communicate directly with potential end-users has thus enabled them to avoid the clutter now complicating communication with health professionals. Second, consumers' interest in the management of their health care has also increased. Pharmaceutical companies have thus argued that DTCA enables consumers to access information about health care options available to them, and thus contributes to a more knowledgeable and healthier society. Finally, some researchers have argued that pharmaceutical companies' motives may be less altruistic than financial For example, Sheffet and Kopp (1990) and Levitt (1995) have argued that the need to generate a return on research and development investments, in particular, created a powerful stimulus for DTCA. This need is particularly acute in countries such as New Zealand, where the proportion of drugs that attract government subsidies is lower than in countries that do not permit DTCA.

Whatever motives underpin DTCA, its presence has generated controversy as drug manufacturers, health professionals and regulators debate whether, and in what form, DTCA should be permitted. In this paper, we first critically evaluate key elements of the DTCA debate occurring in both Australia and New Zealand. We then outline a research agenda we are pursuing that will test many of the competing views about DTCA's effects and, in so doing, provide a more robust foundation for public policy formation.

The Direct To Consumer Advertising Debate

Arguments over DTC have centred on three areas of contention. First, the ethics of promoting restricted medicines to potential end-users who require a prescription before they can obtain the drug (Davis, 2001). Second, the effects DTCA may have on government allocated pharmaceutical budgets, which arguably struggle to meet current demand without having also to accommodate the DTCA generated demand (PHARMAC, 2001). Third, the quality of information provided and consumers' ability to comprehend this (Morris, Brinberg, Klimberg, Rivera and Millstein, 1986*)*. In particular, the emotional appeals used in some advertisements, together with a lack of detailed risk information, have fuelled concerns that some DTCA does not meet the high standards of social responsibility prescribed for it.

Doctor-Patient Relationships

Doctors and health professionals have traditionally opposed DTCA because they believe it disrupts the relationships doctors have with their patients (Lexchin, 1999; Mansfield, 1999; Reast and Carson, 2001). That is, they fear that patients may demand advertised drugs, when these might not suit them, or where other alternatives, such as "green" prescriptions, could prove more effective (Mintzes, Barer, Kravitz, Kazanjian, Bassett, Lexchin, Evans, Pan and Marion, 2002. A US telephone survey of 1,222 consumers found that 32% of consumers who saw an advertisement for a prescription drug talked with their doctor about the medication, with 26% of those asking for a specific medicine and 71% of these requests being granted (Findlay, 2002). Although most patients accept their doctor's advice, there is some anecdotal evidence that a small proportion do not, and that these latter patients have gone on to seek prescriptions from less scrupulous prescribers, or from alternative sources such as the internet (Lexchin, 1999). However, studies exploring the effect of DTC on patients' relationship with their doctors reveal little evidence of dissatisfaction from patients' perspective (though neither do they completely dispel the existence of "doctor-shopping") (Aitken, 2002).

Furthermore, doctors' initial opposition to DTCA in New Zealand appears to have waned following its introduction, which may suggest their concerns were not realised. For example, surveys of doctors reveal that their reaction to DTCA has mellowed, and submissions by doctors' professional associations to DTCA reviews have recognised that DTCA may foster more informed discussions between patients and doctors (NZMA, 2000; RCNZGP, 2000). Nevertheless, although this evidence suggests a growing recognition that DTCA can improve consumers' knowledge, doctors remain concerned

about some of the creative themes used and the lack of risk information provided in television advertisements (Maguire, 1999).

Although one research trajectory could assess doctors' views of DTCA, this research appears likely to provide little more information than that currently available from industry group submissions or publications. Thus, while further research into this question may help to clarify the existence and level of any tension, it is unlikely that this will produce a clear public policy outcome. For example, identifying any causal role attributable to DTCA is well beyond the scope of such research. Nor will this be able to address wider questions about how doctors ought to manage their relationships with patients. Instead, it is more logical to explore doctors' concerns over the communication effectiveness of DTCA, a point we discuss in more detail below.

Fiscal Implications of DTCA

The second concern raised relates to the fiscal implications of DTCA. Where DTCA increases demand for more expensive drugs at the expense of cheaper generic drugs, it may escalate the overall pharmaceutical drug bill (Wilkes, Bell and Kravitz, 2000). In the US for example, 48% of the $21 billion increase in prescription drug sales between 1999 and 2000 came from the 50 most heavily advertised drugs, out of the approximately 9,850 available on the U.S. market; and prescriptions for these 50 drugs increased by 24.6% compared to just 4.3% for all other drugs (Findlay, 2002). Furthermore, drug companies may use evidence of increased consumer demand for branded unsubsidised drugs to argue that drug funders should subsidise these drugs.

The evidence relating to these claims is more limited, and few, if any econometric analyses have considered whether DTC creates or alleviates pressure on the drugs' budget. In support of the latter claim, some researchers have argued that DTC creates a wider awareness of health issues, which fosters prompter diagnosis and treatment (Aparasu, 2000; Calfee, 2002). This, in turn, reduces the need for the more expensive interventions required when a condition becomes acute. In addition, some researchers have suggested that DTCA increases salience of the promoted brand, thereby fostering treatment compliance and reducing the costs resulting from inadequate compliance (Calfee, 2002).

Both arguments appear plausible; however, there is very little evidence to support either of these potential effects. We plan to model DTCA promotions and prescribing behaviour to explore the relationship between DTCA and drug expenditure and longer-term savings that may be attributable to DTCA. This work will clarify the arguments about DTCA's effects and, in particular, its fiscal implications.

Consumers' Understanding of DTCA

The third concern raised relates to consumers' understanding of DTCA promotions. Detractors of DTCA have argued that lay consumers lack the knowledge necessary to understand and interpret DTCA (ACP & ASIM, 2001). In particular, they argue that only

those with detailed technical training can appreciate the interaction between the promoted drug and any other medication consumers may take. Consumers who are inadequately informed about a particular drug's wider characteristics may thus over-estimate its relevance to their condition and fail to appreciate the risks associated with it. As a result, some consumers may visit their doctors specifically to request drugs that they cannot safely take, thus wasting their time and money (Mansfield, 1999).

Conversely, proponents of DTCA suggest that consumers who seek information about an advertised drug have typically recognised undiagnosed symptoms shown in advertisements (RMI, 2000). Consumers therefore do not require a detailed understanding of a particular drug's properties in order to be able to empathise with the specific symptoms depicted. Although they may mention the promoted drug, if this did not suit their condition, doctors would be able to prescribe an alternative treatment (including a non-drug option). Whatever the outcome, DTCA would have promoted the earlier detection of a condition and this, in turn, may reduce the likelihood of more expensive interventions at a later date. Furthermore, FDA research suggests that very few patients specifically visit their doctor to discuss a DTC promotion; those who discuss a drug they have seen promoted typically do so in the context of a visit for a different condition (Aitken, 2002; Calfee, 2002).

Opponents of DTCA have also argued that the promotions are excessively emotive, and that they emphasise benefit information while providing inadequate guidance about the risks associated with a particular drug. Thus consumers may be swept away by the perceived benefits of a product and yet have little comprehension of the risks, side effects, or contraindications associated with that drug. A recent U.S. study that analysed 67 DTCA magazine ads found that 67% used emotional appeals and only 13% provided data (rather than vague qualitative descriptions) on the benefits of the medication (Woloshin, Schwartz, Tremmel and Welch, 2001). Clearly, consumers need to have sufficient knowledge of a drug to make an informed choice whether to seek additional information. Where the details provided do not support this choice, the advertising has arguably failed to meet a high standard of social responsibility (a feature of the legislation or self-regulatory codes in those countries where it is permitted).

Finally, the format in which drug information is presented has also attracted criticism. In New Zealand, advertisers must include information about the drug's active ingredients, its indications, contra-indications, adverse effects and risk factors. In addition, they must specify its status, include standard precautionary information and outline further contact details. While this information can be easily incorporated into print advertisements, it has the potential to overwhelm television advertisements, which may screen for only 30 seconds. To ensure adequate time for the creative content of an advertisement, these technical details typically appear in an end-screen that features for five seconds. Given the amount of information DTC promotions are legally required to contain, consumers may have very little time in which to absorb and comprehend key details about the promoted drug. Research examining consumers' knowledge of key drug properties following exposure to an advertisement suggests many have an inadequate understanding

of the characteristics that would determine the drug's suitability for their condition (Morris *et al*, 1986).

In summary, opponents of DTCA argue that DTC promotions fail to communicate important information, leaving consumers inadequately prepared to assess the relevance or suitability of a drug for their range of conditions. They thus argue that, because a little knowledge can be a dangerous thing, regulators should ban DTCA or, at the very least, impose tighter regulations on it.

Overall, these arguments suggest that further research into the communication effectiveness of DTC promotions is urgently required. At present, our research is exploring the amount and type of information conveyed in DTC promotions, and the format used to convey this, to identify a "best practice" model. We are also examining consumers' knowledge of further information sources (such as free phone numbers) and recall of drugs' key risks and contraindications. In addition, our work assesses consumers' uptake of benefit and risk information, and the extent to which this reflects the "fair balance" criterion DTCA must address. We will also explore how different creative themes affect uptake of information, again with a view to identifying a range of optimal communication formats. This work has specific public policy implications and will help regulators determine whether and how to continue these promotions.

Conclusions

While there are several avenues of research in DTCA that researchers could pursue, we suggest there is little to be gained by pursuing some of these. In particular, further work into health professionals' attitudes toward DTCA will not support public policy decisions, which need to consider effects rather than emotions. Researchers thus need to examine how effectively DTC promotions communicate, and how changes in the structure and content of DTC advertisements could achieve higher standards of communication. This work would address issues raised by health professionals, whose chief concern relates to inadequately informed consumers. Furthermore, in New Zealand, where government regulators have taken a strong interest in DTCA, such research would provide valuable public policy insights. In particular, it could help establish an empirical framework that advertisers could use to help ensure their promotions communicated clearly and effectively, and actively contributed to a better-informed consumer sector.

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